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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/466,698 06/06/95 SANSONETTI P 2356.0043-02

HM12/0330
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EXAMINER

NAVARRO, A

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/466,698

Applicant(s)

Sansonetti et al

Examiner

Mark Navarro

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jan 27, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8, 10, and 13-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 10, and 13-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

Continued Prosecution Application

1. The request filed on January 27, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/466,698 is acceptable and a CPA has been established. An action on the CPA follows.

Applicant's amendment after final filed on September 9, 1999 (Paper Number 34) has been entered as requested in Applicant's CPA request.

Applicant's attention is drawn to the amendment filed April 17, 1998 (Paper Number 25) in which Applicant inserted new claims 15-24. After claim 21, Applicant's have inserted claims 23 and 24. Under rule 1.126 these claims have been renumbered as claims 22 and 23, respectively. Consequently claims 1-8, 10, and 13-23 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-8, 10, and 13-23 under 35 U.S.C. 112, first paragraph, is maintained.

Applicant's are asserting that the claims have been amended to recite that the gene is inactivated "other than by inactivation by means of a transposon inserted into the genes."

Applicant's are further reasserting that the mutagenesis technique taught by the specification does not require knowledge of the nucleotide sequence of the target genes, does not require knowledge

Art Unit: 1645

of regions of genes responsible for biological activity, and the number of nucleotides deleted or inserted is not critical to the practice of the claimed invention. Applicant's further assert that the method of Prentki and Krisch is not transposon mutagenesis, but an alternative to transposon mutagenesis involving an interposon. Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's assertions that the claims have been amended to recite "other than by inactivation by means of a transposon inserted into a gene" is sufficient to render the teachings of Prentki et al irrelevant are correct. However, Applicant's arguments concerning the mutagenesis technique taught by the specification does not require knowledge of the nucleotide sequence of the target genes, does not require knowledge of regions of genes responsible for biological activity, and the number of nucleotides deleted or inserted is not critical to the practice of the claimed invention, are not found to be fully persuasive in view of the teaching of Baudry *et al* (Submitted by Applicant's October 9, 1997, Paper Number 20, Exhibit 2) which set forth that "The available data indicate that the invasive ability of *S. flexerini* is a very complex phenomenon which involves many genes and a large array of polypeptides" and "Whether all these gene products are directly involved in the interaction with the cells, or whether a pool of polypeptides is necessary for transformation and/or correct positioning of a unique product is yet not known." (See page 3411). In view that Baudry *et al* set forth that the invasive ability of *S. flexerini* involves many genes, and that it is unclear whether all these gene products, or some unknown combination of these gene products are directly involved in the interaction with the cells, one of

Art Unit: 1645

skill in the art would be forced into undue experimentation to determine which genes or combination of genes, and which modifications can be made to inactivate genes is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue, (Ex parte Forman 230 U.S.P.Q. 546 (Bd. Pat. App. & Int. 1986)). For reasons of record in Paper Number 36, as well as the above cited reasons this rejection is maintained.

3. The rejection of claims 13-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicant's assert that "the broader concept that Tox-Shigella other than SC501, SC504, SC504, and SC506 could be generated by minor modification of Applicant's methods would naturally occur to the skilled artisan." Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the claim language of claim 13 which recites "wherein said *Shigella* is other than those designated SC501, SC504, SC505, and SC506." While Applicant's set forth in the specification that "various modifications" can be made in the method and vaccine" this does not provide support for claiming an entire genus of the species "*Shigella*" based on the teaching of the preferred embodiments of individual species designated SC501, SC504, SC505, and SC506. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d

Art Unit: 1645

111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.” For reasons of record in Paper Number 36, as well as the above cited reasons, this rejection is maintained.

The following new grounds of rejection are applied to the claims:

Art Unit: 1645

Claim Rejections - 35 USC § 112

4. Claims 1-8, 10, and 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of so that it cannot “substantially invade” cells of a host and cannot spread “substantially” within infected cells and from infected to uninfected cells of the host and cannot produce toxins that will kill “substantial numbers” of the host’s infected, as well as uninfected, cells. One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what degree of invasion is required to meet the threshold for “substantially invade” similarly, what level of invasion would fall short of “substantial invasion?” Likewise how many cells can be killed prior to reaching “substantial numbers” of cells, (e.g., 100, 1,000, 10,000, etc.)? Without a clear definition as to the metes and bounds of the terms “substantially” one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1645

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 17-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,762,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is directed to modified strains of *Shigella* that can be used for making a vaccine against the wild strain of *Shigella*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Dr. Anthony Caputa can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Art Unit: 1645

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

March 28, 2000